

III. REMARKS

Claim 1 is amended to correct grammatical errors. Claims 4, 6, 8, 9, and 10 have been amended to remove abbreviations. Claim 10 is further amended to correct a typographical error, support for which can be found on pages 16-17, and Figure 2 of the specification.

1. Claim Objections

A. Claims 4, 6, 8, 9, and 10 have been amended to correct informalities

On page 4 of the Office Action, Claims 4, 6, 8, 9 and 10 were objected to for failing to spell out abbreviations before the first use of each abbreviation. The Claims have been amended to spell out the abbreviations.

2. Rejections under 35 U.S.C. § 112

A. Claim 10 has proper antecedent basis.

On page 5 of the Office Action, the Office rejected Claim 10 for insufficient antecedent basis for the limitation Abu (2-aminobutyric acid). The Office suggests amending the claim so that it is dependent on Claim 2 instead of Claim 3.

Applicants point out that Claim 3 is dependent on Claim 2. Therefore, proper antecedent basis exists for the term Abu, and Applicants request that the rejection be withdrawn.

B. Sufficient written description exists for the protease of amended Claim 10.

On page 5 of the Office Action, the Office rejected Claim 10 for insufficient written description of a protease that is capable of cleaving the compound in Claim 10, which was inconsistent with Seq ID 3, and pages 16-17 of the specification. Claim 10 has been amended to correct the typographical error which led to the discrepancy, and now reflects a protease capable of cleaving V/L-X-A↓S/V, which is enabled on pages 16-17 and page 20. Therefore, Applicants request that the rejection be withdrawn.

C. Amended Claim 10 is enabled.

On pages 6-7 of the Office Action, the Office rejected Claim 10 as containing subject matter which was not described in such a way as to enable one skilled in the art to make and/or use the invention. Specifically, the Office has pointed out that the prior art has determined the protease cleavage site consensus sequence is V/L-X-A↓S/V, whereas the sequence of Claim 10 contained an arginine in place of the alanine. Amended Claim 10 contains the alanine. Therefore, Applicants request that the rejection be withdrawn.

3. Rejections under 35 U.S.C. § 102(b)

A. Heath et al. does not anticipate Claims 1-5, 7, 8, and 11.

On pages 7-10, the Office rejected Claims 1-5, 7, 8, and 11 for being anticipated by Heath et al. (U.S. 5,235,039), which discloses a method for rapidly measuring the amount of a hydrolytic enzyme (including a protease) wherein the substrate for said enzyme comprises recognition sites on both sides of the cleavage site (column 11, lines 6-11).

Applicants point out that the instant invention differs from the method described in Heath *et al.* The instant invention contemplates the use of fluorescence polarization as a detection method, rather than the fluorescent technology described in Heath *et al.* On page 3 of the specification, Applicants describe the following:

However, fluorescence based assays, especially for screening natural products libraries, have many disadvantages associated with them, especially interference from high fluorescence background. Fluorescence polarization is a detection method that ratios the intensities of vertically versus horizontally polarized fluorescence from a sample that has been illuminated with plane polarized light.

This fluorescence polarization step is specifically set out in Claim 1, from which 2-5, 7, and 8 are dependent, and in Claim 11. Although the Office is correct that “comprising” language can permit additional steps, the opposite is not true; steps recited in a claim must be present in a reference for it to be anticipatory. (MPEP 706.02) Therefore, the Heath *et al.* reference does not anticipate, nor does it suggest or teach the present invention.

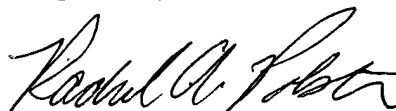
4. *Rejections under 35 U.S.C. § 103*

A. **Claims 1- 11 are not obvious.**

The Office rejected claims 1-11 as being obvious over Heath *et al.*, in view of Welch *et al.* (PNAS 1991) or Blakeslee *et al.* (J. of Immunol. Methods 1976). Heath *et al* discloses the use of fluorescence detection, a substantially different technique that the fluorescence polarization method of the present invention. Therefore, nothing in the Heath *et al.* reference, nor in Welch *et al.* or Blakeslee *et al.* suggests or teaches the fluorescent polarization method for determining protease activity, as in the present invention. Therefore, the present invention is not obvious.

It is therefore submitted that Claims 1-11 are now in condition for allowance. If the Office has any further comments or concerns, the Examiner is welcome to contact Applicants at the number below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Rachel A. Polster", written in a cursive style.

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